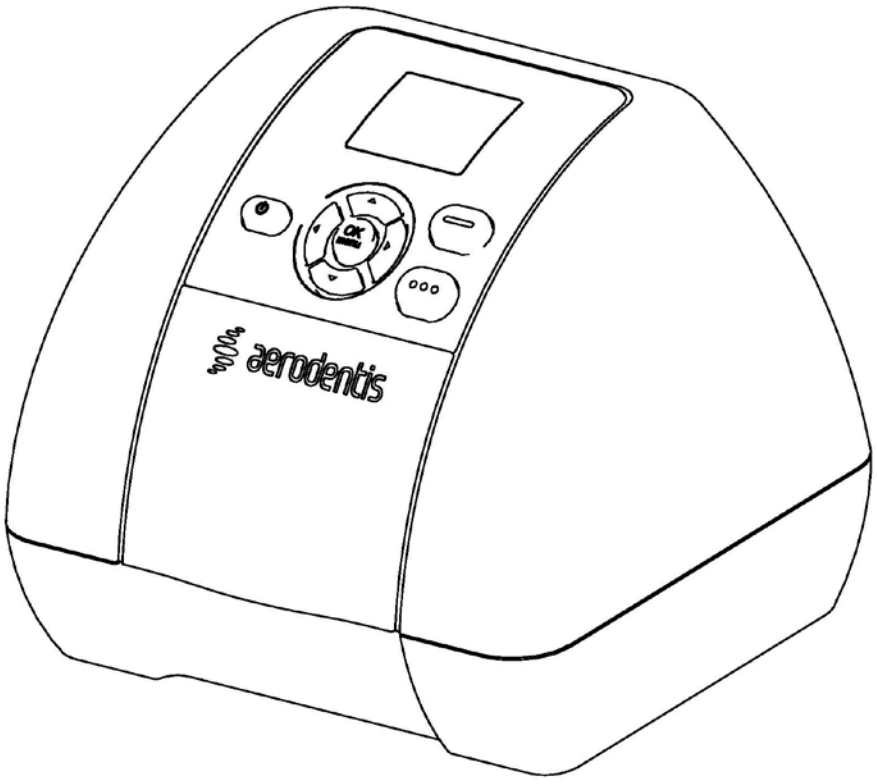
INSTRUCTION MANUAL

Aerodentis Orthodontic System

Model – **PTC4**



ENGLISH

Dror Orthodesign Ltd

Aerodentis

Dental Practioner Instructions for Use

Revised Oct 2012
Software Version 1.2.3
Cat. Num. 4.1

PATENTS

Several patent applications have been filed covering the technology embedded in the Dror Orthodesign Aerodentis System.

DISCLAIMER

The Aerodentis System should only be used in the manner prescribed in this Instructions for Use Changes or modifications not expressly approved by Dror Orthodesign Ltd.or use of the device in any other manner than indicated in this manual could affect the safety or effectiveness of the Aerodentis System and void the system's warranty.

Neither Dror Orthodesign Ltd. nor any of its shareholders, directors, employees or affiliates, shall be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of this device other than that which adheres to the instructions and safety precautions contained herein and in all supplements hereto and according to the terms of the warranty provided in Appendix A.

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1 System Overview

What Is the Aerodentis System?

The Aerodentis System, manufactured by Dror Orthodesign, is intended for the treatment of tooth malocclusion (a condition in which the teeth do not align properly). Tooth malocclusion is treated by applying force, over time, to teeth requiring alignment. Traditionally, the force has been created by attaching brackets to the teeth and creating tension through the stretching of flexible wire connected between the brackets. Alternatively, aligners are used for the treatment of tooth malocclusion. In these devices, a series of mouthpieces are used, where the force created by each mouthpiece on the treated teeth is designed to push the teeth in small, one step increments, toward the desired result.

The Aerodentis System is a individually-fitted, plastic dental mouthpiece that is inserted and worn by the patient according to the dental practitioner's treatment plan. The Aerodentis System is comprised of a plastic mouthpiece containing an inflatable balloon that provides pressure (force) on the selected teeth designed to be moved to a final treated state. The inflatable balloon is inflated to the desired pressure using an electrical air Pump Unit that is programmed by the dental practitioner using Dror Orthodesign proprietary software; thus creating a course treatment specifically designed for each patient.

Intended Use

The Aerodentis System is intended for the treatment of tooth malocclusion in patients with permanent dentition.

Contraindications for Use

Severe open bite; Severe overjet; tooth malocclusion requiring surgical correction, adolescent patients with a skeletally narrow jaw; adult patients in which the malocclusion is periodontally involved; patients with dental implants in moving teeth.

General Risks to Patients

- Dental tenderness may be experienced following Initial aligner placement.
- Gums, cheeks, or lips may be irritated by mouthpiece

- Temporary increase in salvation or dryness of mouth may occur
- The product may temporarily affect speech and may result in a lisp. Speech impediment associated with the product usually resolves within one or two weeks
- Failure to wear the appliances for the required treatment time and/or not using the product as directed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results
- If the prescribed treatment includes interproximal reduction (creation of space to allow for tooth movement) then risks associated with this procedure may be experienced
- Tooth decay, periodontal disease, and permanent markings from stains and decalcification may occur if patients do not brush and Floss their teeth properly before treatment or if foods are consumed while wearing the mouthpiece.
- As with other orthodontic treatments, teeth may shift position after treatment and wearing of retainers at the end of treatment should reduce this movement
- Dental restorations (e.g. crowns) may become dislodged and require treatment.
- A tooth that has been previously traumatized and/or significantly restored may be aggravated by the treatment and in rare instances require additional dental treatment such as endodontic and/or additional restorative work, and/or tooth loss.
- As with all orthodontic treatments, the health of the bone and gums which support the teeth may be impaired or aggravated and the length of the roots of the teeth may be shortened (a threat to the longevity of the teeth).
- In rare instances, problems in the temporo-mandibular joint (jaw joint) may result in joint pain, headaches, or ear problems,
- The bite may change during the course of the treatment and may result in temporary patient discomfort. If a bite change occurred, the bite may require adjustment by the doctor at the end of the treatment.

Electrical Classification

The Aerodentis System complies with IEC 60601-1 and IEC 60601-1-2. The unit is classified as Class II, continuously operated, ordinary equipment with BF applied parts and with signal input output parts. The device is not intended for use in the presence of flammable mixtures. The Device is classified as Portable equipment.

	**WARNING** **The Electrical Air Pump needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents**

	**WARNING** **Portable and mobile RF communications equipment can affect the Electrical Air Pump Unit.**

About this Manual

This manual provides the information necessary to operate the Aerodentis System in a safe and efficient manner. Please read and thoroughly understand the manual before operating the system. If any part of this manual is not clear, contact Dror Orthodesign Customer Support for clarifications.

The manual is intended to serve as an accompanying document to the Aerodentis System.

This manual should always accompany the unit, and should be read and understood in its entirety.

Manual Conventions

The following manual conventions are used throughout the manual.

Warnings, Cautions and Notes

Warnings, Cautions and Notes are used throughout this manual:

	**WARNING** Indicates precautions and instructions which, if not followed, may result in personal injury or death.

	**CAUTION** Cautions indicate instructions, that if not followed may result in damage to the equipment or to the quality of treatment.

	**NOTE** Are used to identify an explanation, or to provide additional information for purposes of clarification

Menus Screens and dialog boxes

The names of menus, screens and dialog boxes are presented in bold

Terms and Acronyms

Non

2 Warnings and Precautions

Before use, carefully read this manual and the precautionary information. Pay attention to the following (and to additional precautionary information that appears elsewhere in the manual) to enable efficient operation of the Aerodentis System, to prevent endangering the system operator and to prevent damage to equipment:

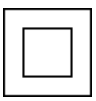
.

-  Handle the Electrical Air Pump Unit with care. Do not drop, knock, or shake the Electrical Pump Unit. Rough handling can break internal circuit boards.
-  The Electrical Air Pump Unit is not water-proof. Keep the Control Unit dry.
-  The System is intended for indoor operation only.
-  Damaged System should not be disposed as unsorted municipal waste. Please contact your local distributor for unit disposal.
- The Aerodentis System should be serviced only by qualified service personnel, authorized by Dror Orthodesign Ltd.
- In the event that the Aerodentis System does not operate properly, contact Dror Orthodesign Ltd. customer support.
- Do not use water or any other liquids to clean the Electrical Air Pump Unit.
- Do not operate the charger with a damaged cord or plug. If damaged, have the charger replaced immediately by a qualified service technician. Following this rule will reduce the risk of electric shock, fire, or serious personal injury.
- The Electrical Air Pump Unit should be used only with the Aerodentis mouthpiece.
- Do not attempt to replace the batteries. Battery replacement should be performed by Dror Orthodesign Ltd personnel only and not by the user.

- Changes or modifications not expressly approved by Dror Orthodesign Ltd. could affect the safety or effectiveness of the System and void the system's warranty.
- Do not disassemble the charger. Only a Dror Orthodesign technician is authorized to service the device.
- Do not expose to direct sunlight.
- Do not use a damaged System. Use of damaged components might result in malfunctioning of the System.
- The Aerodentis System should be installed and serviced only by qualified service personnel, authorized by Dror Orthodesign Ltd.
- Do not open the system covers.

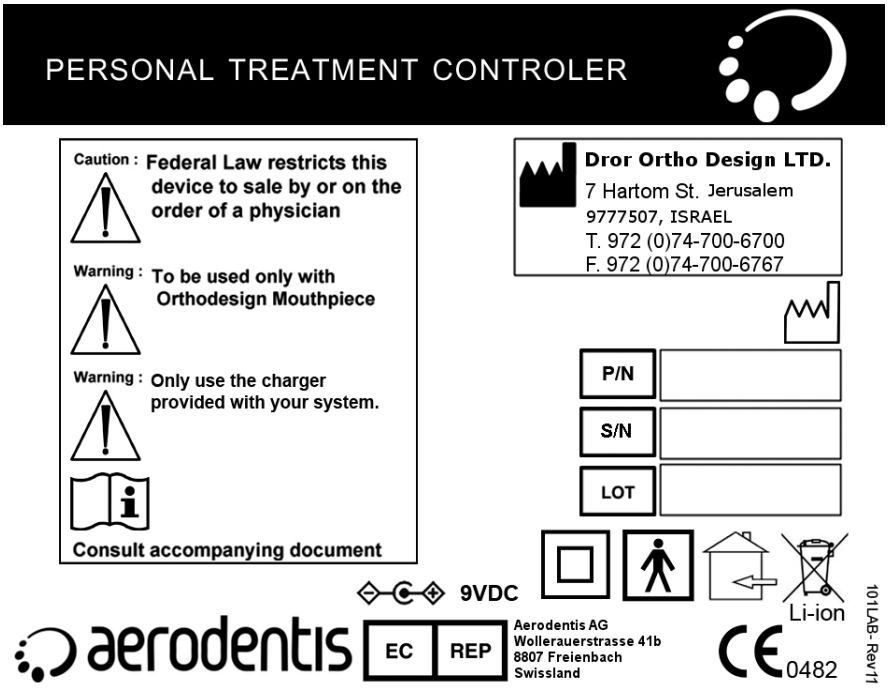
3 System Labels

The following provides a description of the graphical symbols that appear on the Aerodentis System components and packaging.

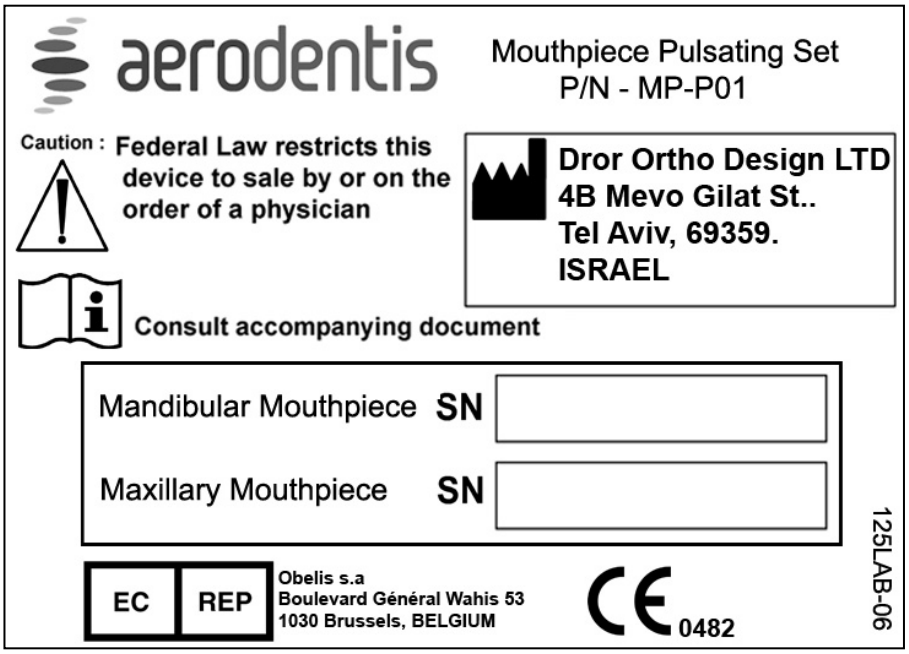
	Warning
	Caution
	Consult Accompanying document
	Type BF applied part
	Fragile, handle with care
	Keep dry
	Indoor operation only
	Sorted disposal
	Class II - has been designed in such a way that it does not require a safety connection to electrical earth

The following labels are affixed to the system:

Personal Treatment controller Label



Mouthpiece Label



4 System Description

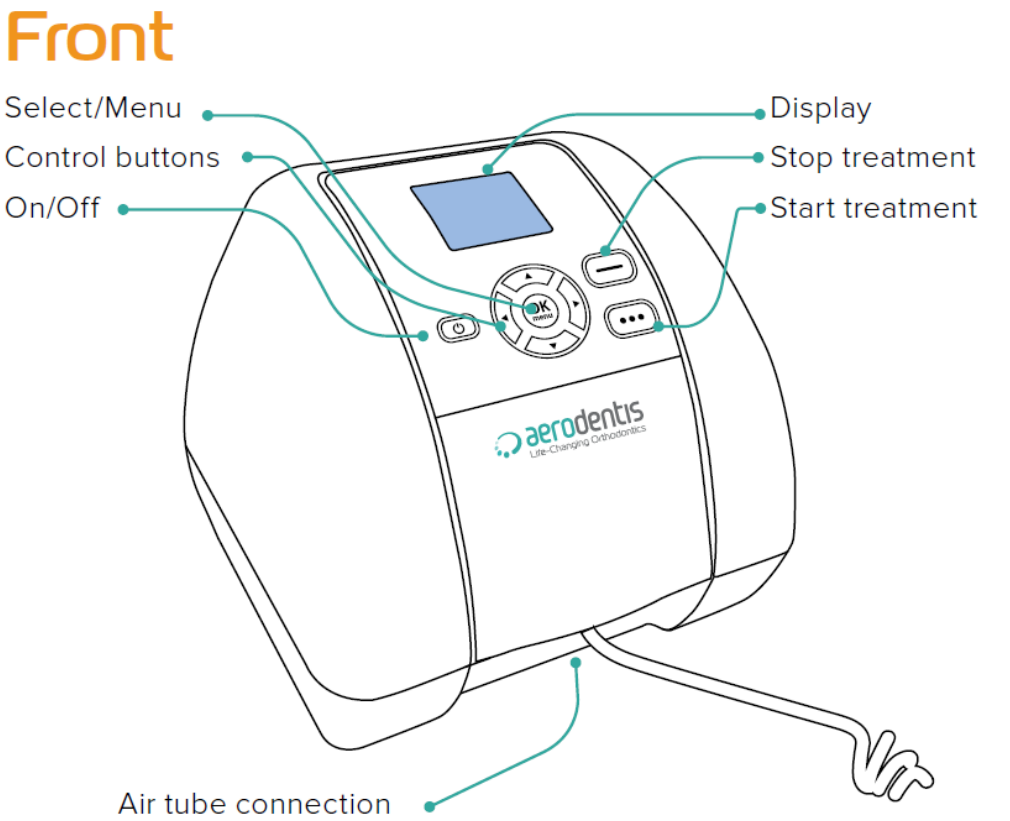
Introduction

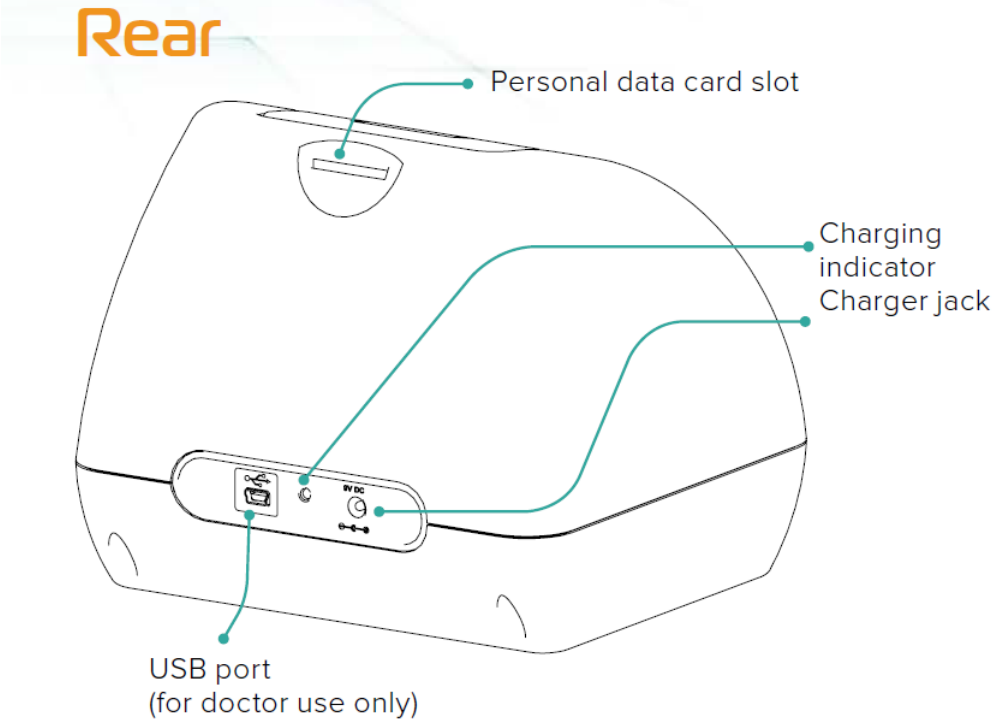
The Aerodentis System applies force on selected teeth requiring realignment. The amount of force is determined by the dental practitioner and is applied to the teeth by means of a pressure element (inflatable balloon) contained within the individually-fitted mouthpiece. The mouthpiece attaches to the electrical air pump unit via a polyurethane hose until the inflation of the balloon contained in the mouthpiece reaches the desired pressure (pre-set according to the dental practitioner). Through repeated use of the device (~14 hours daily), applied force repositions each tooth from its original state to the predetermined, final tooth position via a track-per-tooth mechanism. Pneumatic pressure (force) may be applied on the buccal or lingual surfaces of each individual tooth undergoing treatment.

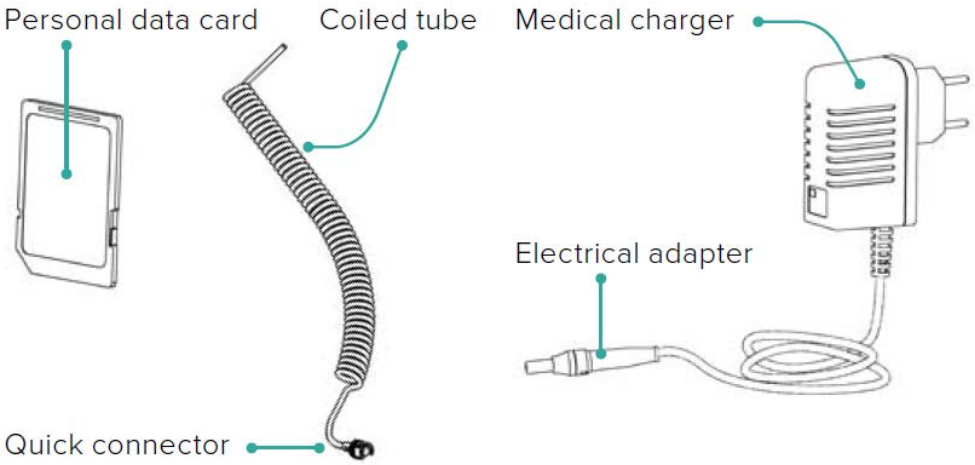
The device is designed to be used for 10-14 hours per day for a period of approximately 1.5 years

System Components

The system consists of the following components:







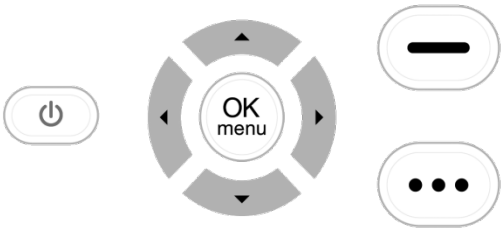
Personal Treatment controller (PTC) :

The PTC includes the following components:

- LCD Screen
- Seven control buttons
- SD Card socket
- Pressure outlet – tube connector
- DC connector for charger (supplied)
- Mini USB female connector
- Charging indication green led
- Rechargeable battery

User Interface

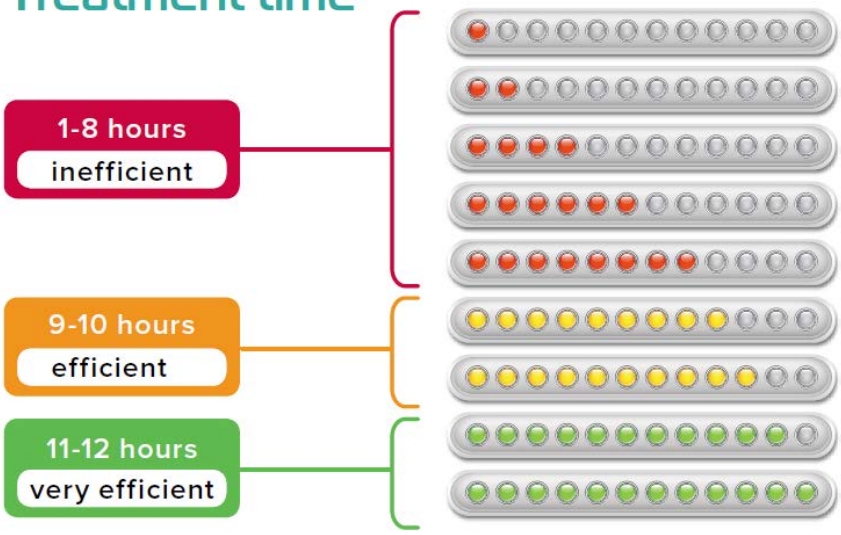
Navigating the Manu and actions can be done by using the direction keys.



Personal Usage Meter

For your convenience, the control console is equipped with a personal usage meter to keep track of your daily treatment hours. While operating, the usage meter is presented as 12 black dots on the system screen. For each hour of treatment, the back changes color. The color of the dots indicates the number of hours operated.

Treatment time



* The usage meter is reset every morning at 12:00 AM.

Mouthpiece

The mouthpiece is based on an initial mold of the patient's teeth, taken by the dental practitioner. Subsequent molds and the final mouthpiece are formed using ‘off the shelf’ software by digitization of the initial mold. The mouthpiece is worn by the patient prior to balloon inflation. The individually designed mouthpiece fits the teeth snugly, anchored by the retention clasps, on non-treated teeth. The space created by the track-per-tooth mechanism (difference between the teeth and the final treated state) with the force from the inflatable balloon allows for movement of teeth for which movement is intended.

The inflatable balloon is located in a predetermined position in the mouthpiece and has limited range of motion to ensure that pressure is applied in the desired direction on the treated tooth. When inflated, the balloon fills the pre-designed opening and ensures that pressure is applied against the tooth to which it is in contact. In this manner, pressure is applied to the entire surface area of the tooth that is exposed to the balloon (

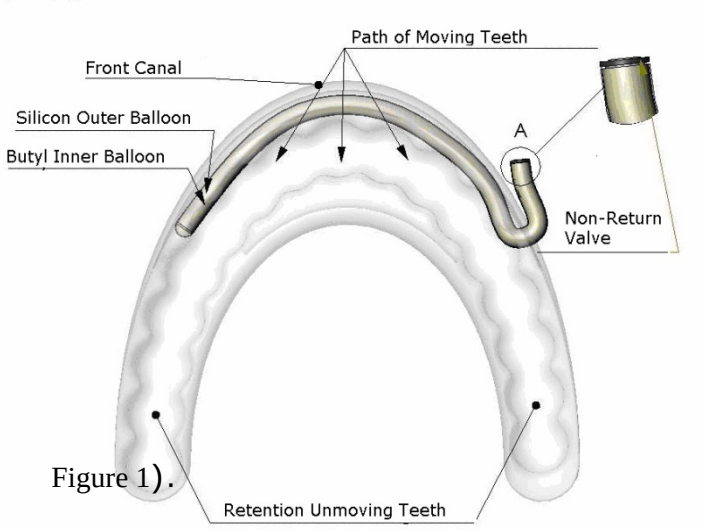


Figure 1).

Depending on the desired direction of tooth movement, the pressure element (inflatable balloon) is designed either be bucall or lingual.

Polyurethane Tubing

The Polyurethane tubing is used to connect between the Mouthpiece and the Electrical Air Pump Unit.

5 System Operation

Using the Mouthpiece

When you are going to sleep you should use the Aerodentis treatment system in a Pulsating Pressure Mode.

In PPM the PTC is permanently connected to the mouthpiece with the connecting tube and performing pulsating treatment by changing the amount of air in the internal balloon during all night.

WARNING

Check that the system is not damaged visually prior to use.

1. Brush your teeth and rinse the mouthpiece with lukewarm water before insertion.
2. Place the mouthpiece on your teeth and make sure that it fits securely.
3. Make sure that the flexible tubing end is connected to the Electrical Air Pump Unit and make sure that it is locked in place

NOTE

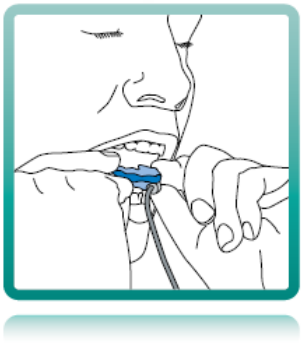
If the tubing is loose or disconnected insert the tube into the connector and it will lock automatically. For tube disconnection press the connector tip and pull the tube gently.

4. Connect the tube from the end of the mouthpiece to the quick disconnect coupling on the end of the spiral tube
5. Turn on the PTC unit by pressing power button (⏻).
6. To start Pulsating inflation, press pulsating treatment button (•••) once
7. The PTC will start working to inflate and deflate the balloon in the programmed parameters, during the pulsating mode you should see progress bar blink with dots according to your progress

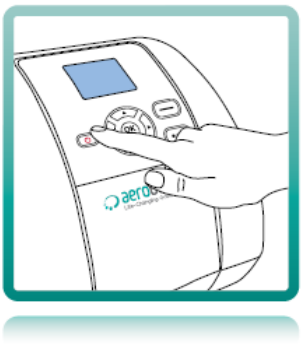
8. Once the treatment is completed, the PTC will turn off automatically.
9. Disconnect the tube from the Mouthpiece.
10. Take the mouthpiece off your teeth.
11. Rinse the mouthpiece in water

	NOTE The Mouthpiece must remain on the teeth throughout each treatment period (10-14 hours).
	CAUTION While the mouthpiece is in use, do not drink, smoke or eat.

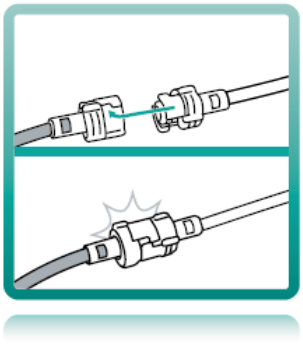
1. Place the personal dental device on your teeth. Check that it is firmly in place.



3. Turn on the control console with the On button.



2. Attach the quick connector to the end of coiled tube until you hear a "click."

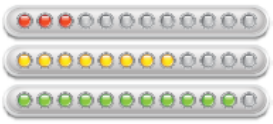


4. Press the "Start Treatment" button

Instructions (cont)

5 During the treatment

Confirm that the **usage meter** display is flashing and the time counter advances.

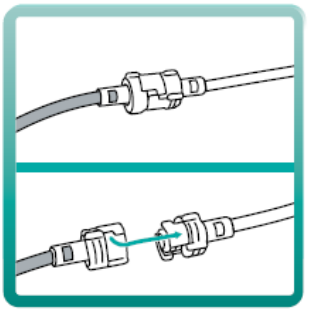


6 At the end of the treatment

Confirm that all the usage meter dots are illuminated green.
Red or orange lights indicate that there has not been enough treatment time in the last 24 hours.

7 Stopping the treatment

You can stop the operation of the control console at any time by pressing the Stop treatment button.
or by disconnecting the quick connector from the personal dental device.



6 Maintenance and Cleaning

Care of the Mouthpiece

- Wash your hands before handling the mouthpiece
- Clean the mouthpiece every day by washing it with water.
- Rinse the mouthpiece before insertion.

	**WARNING** Do not use strong solvents (thinner, benzene, etc.) or abrasive cleansers or hot or boiled water for washing the device.

Cleaning the Electrical Air Pump Unit

Only clean the exterior of the Electrical Air Pump Unit using a cloth dampened with water.

	**WARNING** Never open the Electrical Air Pump Unit housing as this may damage the System.
	**WARNING** Avoid placing liquids or food on any part of the System. Do not allow conductive fluids to leak into the active circuit components of the System as this may cause a short circuit, which could result in an electrical fire. In this event, only fire extinguishers approved for use on electrical fires should be used.
	**CAUTION** Handle the Electrical Air Pump Unit with care. Do not drop, knock, or shake the Electrical Air Pump Unit. Rough handling can break internal circuit boards.

7 When to Contact Your Doctor

If any of the following situations occur, immediately stop using the device and contact your doctor:

- If you are experiencing sharp pains or bleeding in your mouth.
- If you don't hear air being released when you insert the Air Release Adaptor.
- If the device repeatedly shuts down when attempting to connect the Electrical Air Pump Unit to the Mouthpiece.

8 Charging the Battery

The following icons on the electrical air pump unit display indicate the battery status:

	Full battery (Green)
	Almost full
	Low—recharge before use
	Battery empty
	Charging mode

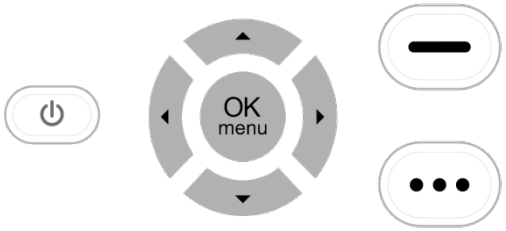
	**WARNING** Do not attempt to replace the batteries. Battery replacement should be performed by Dror Orthodesign personnel only and not by the user.
	**WARNING** Only use the charger provided with your system. Never try to connect any other device and/or cable to the Charging connector of the Electrical Air Pump Unit (e.g. telephone device or cables).

The battery should be charged whenever it is in the low or empty state. Plug the Recharger into the socket in the bottom of the Electrical Air Pump Unit on one end, and into the electrical socket on the other.

9 Menu and Advanced settings

Some parameter can be changed in the Menu area.

1. Turn on the PTC (⏻)
2. Press the Manu button (OK menu)
3. The first menu screen will show, you can navigate through the menu screen by using the up and down keys.

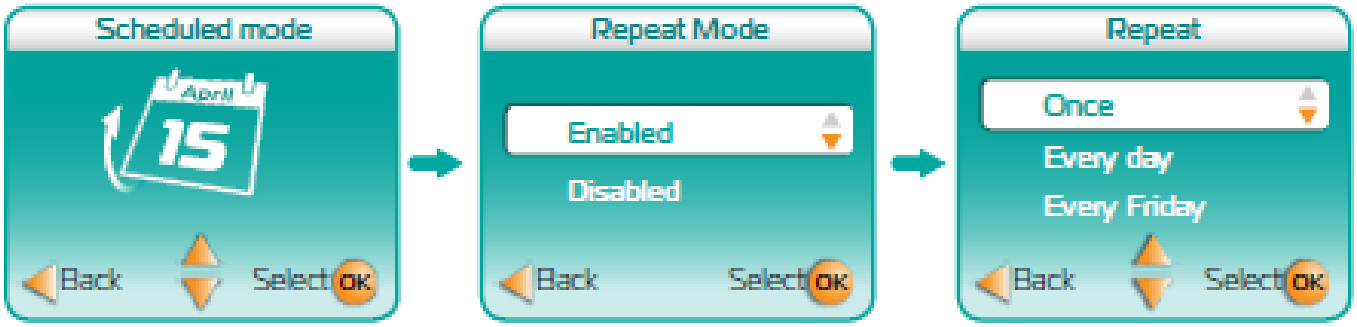


Time/Date

The internal clock is factory-set. If the control console's internal battery runs out, reset the time and date from this menu. Adjust the time and date using the arrow buttons. When completed, press **OK**.

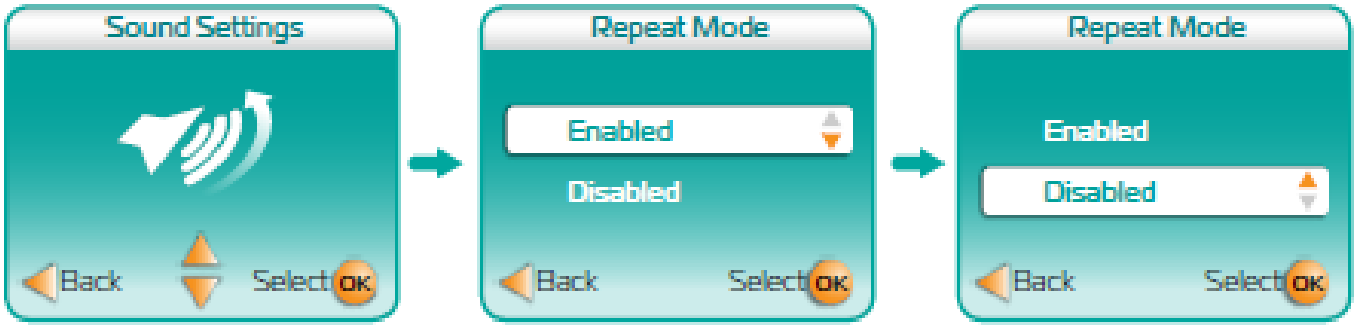
Automatic Operation/Reminder

You can preset the system to operate automatically at a specific time and date, or preset it for one time only. Select **Enable**. Choose the start time, end time and frequency: once only, every day or for Friday night.



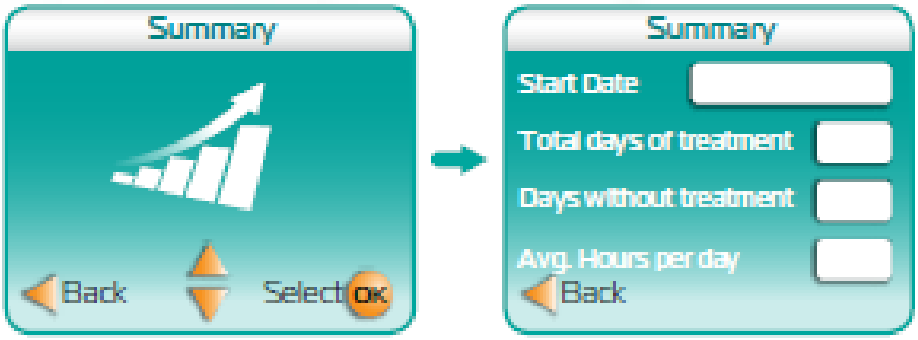
Key and System Tones

You can turn off all system tones by changing the status to **Disabled**. To reactivate system tones switch to **Enabled**.



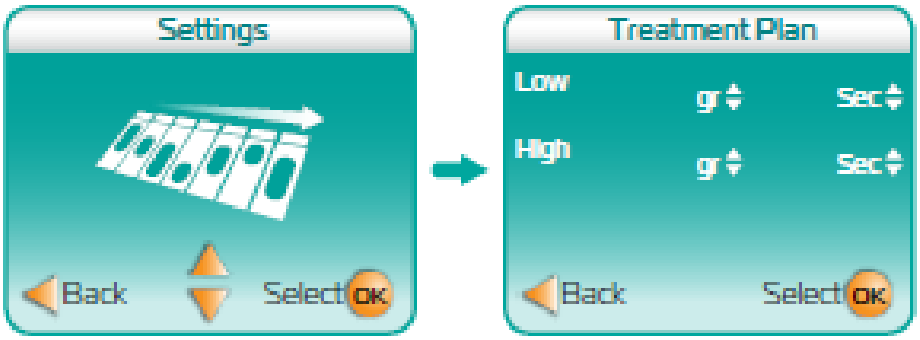
Cumulative Usage Meter

Displays all data that has accumulated during the course of your treatment.



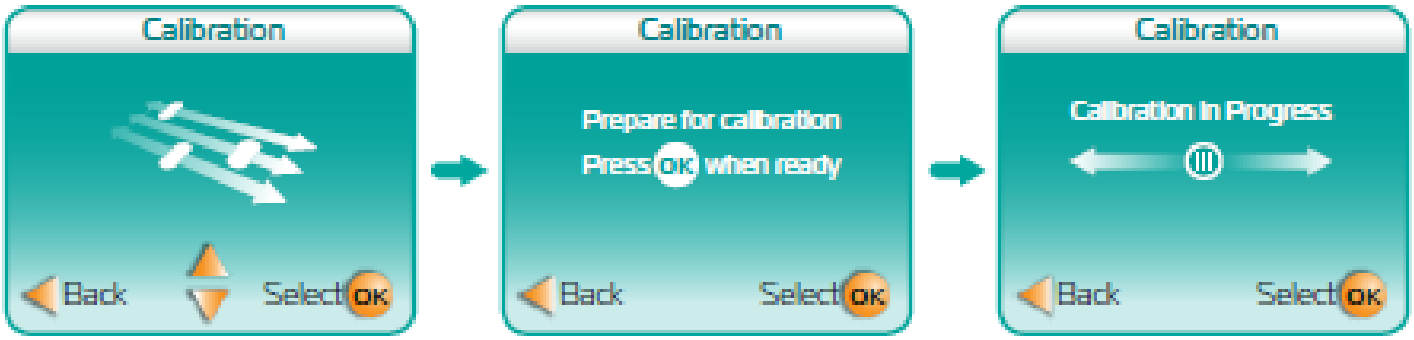
Treatment Program

Displays your personal treatment program prescribed by your doctor. It details the force exerted and the frequency of the pulsated force prescribed.



System Calibration

Please calibrate the control console for each new personal dental device. After the personal dental device has been placed on your teeth, begin the calibration process. Make certain the calibration is completed and indicated on the display.



10 Frequently Asked Questions

How does Aerodentis work?

The Aerodentis system relies on the same biomechanical principles of traditional orthodontics: applying force to move your teeth to the desired position. Instead of applying constant, uniform force through metal braces or aligners that must be periodically tightened or readjusted, Aerodentis works by using air pressure to move your teeth gradually while you sleep. Because this pulsed air pressure works more effectively than constant force, only approximately 10 hours per day of active treatment is needed.
The rest of the time, you are completely free from any orthodontic devices!

What if I sleep for less than the hours I need to wear the device?

The Aerodentis system is designed for primary use while at rest. It is the most comfortable and easiest way to perform treatment.
Of course, if more time is needed to complete the minimum hours your doctor determined, just pick the time and place that is best for you - watching television, working on the computer or studying.

What happens if I wear the Aerodentis device more than 10 hours a day?

Applying Aerodentis treatment for more than 10 hours a day will accelerate treatment progress. Of course, this should only be done after consulting your doctor.

What happens if I wear the Aerodentis device less than 10 hours a day?

Applying Aerodentis treatment for less than 10 hours a day, or the number of hours your doctor prescribes, will slow down

the progress of your treatment. Each individual has a minimum cut-off point. Treatment hours below this point will
render the treatment ineffective.

Why is the pulsated air pressure so important?

The concept behind using pulsating orthodontic force has been clinically proven. Studies have shown that a device with pulsating
force moved the teeth faster than continuous force. Studies using animal models have further demonstrated the benefits of
pulsating force compared to continuous force. The Aerodentis device features programmable pulsating force. This enables your
doctorto prescribe each patient an accurate force level and pulsating cycles according to the initial progress of teeth movement.
Based on previous clinical and research data applying pulsating force does not cause hyalinization and necrosis. This may potentially
decrease the risk of root resorption, a common problem with conventional braces.

Is Aerodentis treatment painful?

No. The gentle pulsating action mimics our body's natural rhythm and physiology. Sometime patients feel slight pressure
when first applied. Initially the force is set to be minimal and is gradually increased. These small gradual changes make it more
comfortable and do not cause pain.

How often will I need to visit my doctor?

We recommend that you visit your doctor four weeks after starting your treatment. Sometimes it is necessary to make minor
adjustment to the Personal Dental Device. After that, you will probably only need to visit your doctor once every
three to four months.

Does the Control Console always need to be connected to the electricity while I am sleeping?

No. The internal rechargeable batteries last for approximately 20 hours of operation. But it is completely safe to leave the unit plugged in. The unit complies with the

strictest medical device regulations and standards, including ISO 60601-1, ISO 13585:2003 that permit connection to the electrical current during treatment.

How does the Aerodentis system ensure proper alignment of my teeth?

Your Personal Dental Device is custom-made for each patient. The unique production process uses computerized 3D imaging and
other peripheral technologies that ensure unprecedented accuracy and superior alignment. The production process is governed
by the strictest quality control and meets CE medical grade standards.

What do I need to bring to the doctor's when I come to the doctor's office?

All you need to bring with you is your Personal Dental Device and the smart card from the Control Console.
With this, your doctor has all the information needed, and if necessary, can reprogram your treatment plan.

11 Specifications

Physical Characteristics

Electrical Air Pump Unit	
Dimensions (HxWxD)	145mm x 140mm x 140mm (approx.)
Weight	500 gr
Material	Outer Box : PC/ABS Inner Box : ABS+Talc
Mouthpiece	
Dimensions (HxWxD)	80mm x 60mm x 10mm (approx.)
Weight	10 gr
Materials	Essix A+® Plastic MSDS

Environmental Conditions for Pump Control Unit

Relative Humidity	
Relative Humidity	10% to 95%
Ambient Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage and Transportation	
Temperature Range	-20°C to 45°C (-4°F to 113°F)
Relative Humidity	10% to 95%

Environmental Conditions for Mouthpiece

Operation	
Relative Humidity	100%
Ambient Operating	10°C to 40°C (50°F to 104°F)

Temperature	
Storage and Transportation	
Temperature Range	-20°C to 45°C (-4°F to 113°F)
Relative Humidity	10% to 95%

Pressure Characteristics

Compression Pressure	3-14 ± 0.5 PSi

Electrical

Power	
Voltage Input Range	100-240 VAC, 50-60 Hz
Batteries	7.4V 1800mAh Li-Ion batteries
Fuses (internal)	General
Isolation	N/A

Switches/Indicators

7 Control keys
LCD
Power indication LED

12 Troubleshooting

	Problem	Possible Cause	Solution
1	The Electrical Air Pump Unit does not start	1. No electrical power 2. Discharged Battery	1. Check power in the wall socket 2. Charge the Control Unit, according to the “charge instructions”
2	Air is not being released from the mouthpiece	The air has been already released from the mouthpiece.	Remove mouthpiece and contact your doctor.
3	A Pump Error message appears on the screen followed by buzzer noise and the electrical air pump unit turns off.	1. The tube is not connected properly. 2. Electrical malfunction.	1. Make sure that all connections are tight and try inflation procedure again. 2. Contact your doctor.
4	During Inflation, the mouthpiece pops from its place	The mouthpiece was not placed correctly.	Disconnect tubing, deflate the balloon, take out the mouthpiece and rinse with water. Re-insert the mouthpiece.

13 Compliance with Standards

The Aerodentis System was tested and found to be in compliance with the following standards:

STANDARD	#
Medical electrical equipment- general requirements for safety. Part 1: General Requirements for Safety	IEC 60601-1(1988): +A1(1991) +A2(1995); UL 60601-1 (2003)
Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests	IEC 60601-1-2 (2005)
Programmable electrical medical system Requirements for safety	EN 60601-1-4 (2000)
Medical devices – Application of risk management to medical devices	ISO 14971: 2007
Graphical symbols for use in the labeling of medical devices	EN 980 (2003)
Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied	ISO 15223 (2004)

14 Support and Contact Information

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15 Disclaimer and Limited Warranty

a. Dror Orthodesign Ltd. warrants that the System, with which this manual was delivered, will be free from defects in design, materials, and workmanship for a period of x year from the date of delivery of the System to you. If the System contains a defect in design, materials or workmanship and such System is returned to Dror Orthodesign. within 1 (one) year of delivery of the System to you, Dror Orthodesign will repair or replace the System, or issue a credit for the purchase price of the System, with the choice to repair, replace or credit being within the sole discretion of Dror Orthodesign. The foregoing repair, replacement or credit remedy will be your sole remedy for breach of the warranty set forth in this Section.

b. Limitation of Warranties. The warranties contained in Section a above do not cover damage to the System caused by accident, misuse, abuse, negligence, failure to install in accordance with Dror Orthodesign Ltd.'s installation instructions, failure to operate under conditions of normal use and in accordance with the terms of the documentation accompanying the System, failure to maintain in accordance with applicable documentation accompanying the System, alteration or any defects not related to System design, materials or workmanship. This warranty does not cover damage, which may occur in shipment. This warranty does not apply to Systems not purchased new. This warranty does not apply to any System or any individual parts of a System which have been repaired or altered by anyone other than Dror Orthodesign Ltd. or a person or entity authorized by Dror Orthodesign Ltd. to repair Systems.

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